

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

CAVAZZA Atty. Ref.: 2818-180

Serial No. 10/724,175 TC/A.U.: 1614

Filed: December 1, 2003 Examiner: Henley

For: TREATING CHRONIC UREMIC PATIENTS UNDERGOING

PERIODICAL DIALYSIS

.

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

TERMINAL DISCLAIMER

Your petitioner, Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., a corporation having an office and place of business at 47, Viale Shakespeare, I-00144 Rome, Italy represents that it is the assignee as recorded in an assignment at Reel 011630/Frame 0932, of all right, title and interest in and to Application Serial No. 10/724,175, filed December 1, 2003, for TREATING CHRONIC UREMIC PATIENTS UNDERGOING PERIODICAL DIALYSIS.

Your petitioner hereby disclaims the terminal part of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term as presently shortened by any terminal disclaimer of Patent No. 6,429,230 and hereby agrees that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to such patent granted on the above-identified application shall be the same as the legal title to the above-identified Patent No. 6,429,230, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantee, its successors or assigns.

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Petitioner does not disclaim any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term as presently shortened by any terminal disclaimer of Patent No. 6,429,230 in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321(a), has all claims canceled by a reexamination certificate, or is otherwise terminated prior to the expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

The evidentiary documents accompanying this document or referred to above have been reviewed by the undersigned and it is certified that to the best of the assignee's knowledge and belief, title is in the assignee seeking to take action.

Check either box 1 or 2 below, as appropriate.

- 1. Tor submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.
 - 2. \square The undersigned is an attorney or agent of record.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.

By:

Arthur R. Crawford

Assignee's Attorney

Date: Dec. 21, 2004

"CAVAZZA Serial No. 10/724,175

Terminal disclaimer fee under 37 C.F.R. § 1.20(d) included. If missing, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.